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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,737	09/17/2001	Wolfgang Strittmatter	MERCK 2299	8947

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EXAMINER	
MAYES, LAURIE A	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,737	STRITTMATTER ET AL.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *6-13 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 14-17* is/are rejected.

7)☒ Claim(s) *4, 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5 and 14-17, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the groups of inventions have common utilities such as blocking the adhesion of cells and that a search of the groups of inventions would not represent a serious search burden for the examiner. This is not found persuasive because Group II includes an additional method of use of the protein of Group I to the method of Group I of using the protein for the manufacture of medication. PCT Rules do not provide for multiple methods of use nor is burden of search a criteria for unity of invention under 35 USC 371. The protein in Group I has a different function and structure than the polynucleotide of Group III, the antibody of Group IV and the agonist of Group V as the protein may be used to treat thromboembolic processes while the polynucleotide may be used to encode a protein, the antibody responds to antigens and has immune functions and the agonist may be used to identify compounds which inhibit a polypeptide. The inventions of Group II and Groups III, IV and IV are unrelated as the polynucleotide, antibody and agonist are not used in the method of Group II of using a peptide to coat artificial surfaces and for modifying intraocular lenses. The polynucleotide of Group III has a different structure and function than the antibody and agonist of Groups IV and V as the polynucleotide may be used to encode a protein while the antibody responds to an antigen and the agonist may be used to identify compounds which inhibit polypeptides. The antibody of Group IV has a different structure and function than the agonist of Group V as the antibody responds to antigens and has immune functions while the agonist may be used to identify compounds which inhibit polypeptides. Because these inventions are

distinct for the reasons given above and have acquired a separate status in the art as shown by their different subject matter and searches required for each, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Abstract

The abstract of the disclosure is objected to because tape is covering the language on the left side of the page. Correction is required. See MPEP § 608.01(b).

Oath/Declaration

Page 1 of the declaration is not fully legible as tape is covering the language on the left side of the page.

Specification

The specification is objected to because the term "sofaras" has been misspelled (p. 5 of specification, line 28). Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 2 is objected to because of the following informalities: the symbol designating "plus or minus" should read "±". In claim 4, the "SEQ ID NO. 1" should be "SEQ ID NO: 1" (no periods). See also other pending claims 5, 7, 12 and 22.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "capable of forming –S-S- bridges" is vague as it is unclear whether the bridges are formed.

Claim 17 provides for the use of a polypeptide for the manufacture of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 14, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolstoshev et al. (US 5,705,355). Tolstoshev et al. teach a hirudin or hirudin analog polypeptide isolated from H. medicinalis (col. 1, lines 22-23) having a molecular weight of about 12,000 kD (col. 2, lines 28-30) with the biological activity of an inhibitor of platelet adhesion (col. 1, lines 65-66) (present claim 1) wherein the polypeptide has at least six cysteine residues capable of forming –S-S- bridges (col. 15, lines 35-39) (present claim 3). Orevi et al. (US 5,246,715) is cited of record to show that hirudin is known in the art to inhibit collagen-induced platelet adhesion (col. 3, lines 6-20). Tolstoshev et al. also teach a pharmaceutical formulation comprising the polypeptide and a pharmaceutically acceptably carrier (claim 4 and col 7, lines 34-42) (present claims 14 and 17) for the treatment of thromboembolic processes (see claim 5) (present claim 15). Tolstoshev et al. teaches all of the elements of claims 1, 3, 14, 15 and 17 and these claims are anticipated under 35 U.S.C. 102(b).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich et al. (US 5,523,287) in view of Tolstoshev et al. Friedrich et al. teach a pharmaceutical preparation for the treatment of thromboembolic processes (col. 1, lines 5-10)(present claims 14, 15, 17) comprising a polypeptide that inhibits thrombin and that itself treats thromboembolic processes, hirudin with a pH of about 3.5 (col. 7, lines 10-11)(present claim 2) and streptokinase (col. 2, lines 22-25)(present claim 16) for an increased thrombous specificity (col. 2, lines 29-31). Friedrich et al. do not teach specifically a polypeptide having a molecular weight of 12,000 kD.

Tolstoshev et al. teach a polypeptide isolated from H. medicinalis (col. 1, lines 22-23) having a molecular weight of about 12,000 kD (col. 2, lines 28-30) with the biological activity of an inhibitor of platelet adhesion (col. 1, lines 65-66) (present claim 1). Tolstoshev et al. does not teach a pharmaceutical preparation containing the polypeptide that also contains aspirin, heparin or streptokinase.

Given the advantages of using hirudin with a pH of about 3.5 to treat thromboembolic diseases and the further advantages of an increased thrombous specificity in the treatment of thromboembolic disorders by combining streptokinase and a protein that inhibits thrombin as taught by Friedrich et al, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a peptide isolated from H. medicinalis having a molecular weight of about

12,000 kD and a pH of about 3.5 with streptokinase as an inhibitor of platelet adhesion. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-3 and 14-17 are rejected. Claims 4 and 5 are objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
June 25, 2003

Christopher Low

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